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Elektrisk utrustning för medicinskt bruk - Säkerhet - Del 1: Allmänna fordringar - 4. Tilläggsstandard: Programmerbara utrustningar och system

Medical electrical equipment - Part 1: General requirements for safety - 4. Collateral standard: Programmable electrical medical systems

Som svensk standard gäller europastandarden EN 60601-1-4: 1996. Den svenska standarden innehåller den officiella engelska språkversionen av EN 60601-1-4: 1996.

Nationellt förord

Europastandarden EN 60601-1-4: 1996

består av

- **europastandardens ikraftsättningsdokument,** utarbetat inom CENELEC
- **IEC 601-1-4, First edition, 1994 - Medical electrical equipment - Part 1: General requirements for safety - 4. Collateral standard: Programmable electrical medical systems**

  utarbetad inom International Electrotechnical Commission, IEC.

Denna svenska standard utgör en tilläggsstandard till SS-EN 60601-1, Elektromedicinsk utrustning - Säkerhet - Del 1: Allmänna fordringar, och dess separat utgivna tillägg.

ICS 11.040.00

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-1-4

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English version

Medical electrical equipment
Part 1: General requirements for safety
4. Collateral standard: Programmable electrical medical systems
(IEC 601-1-4:1996)

Appareils électromédicaux
Partie 1: Règles générales de sécurité
4. Norme collatérale: Systèmes électromédicaux programmables
(CEI 601-1-4:1996)

Medizinische elektrische Geräte
Teil 1: Allgemeine Festlegungen für die Sicherheit
4. Ergänzungsnorm: Programmierbare, elektrische, medizinische Systeme
(IEC 601-1-4:1996)

This European Standard was approved by CENELEC on 1996-07-02. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CENELEC member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the Central Secretariat has the same status as the official versions.

CENELEC members are the national electratechnical committees of Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

CENELEC

European Committee for Electrotechnical Standardiration
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

Central Secretariat: rue de Stassart 35, B - 1050 Brussels

Ref. No. EN 60601-1-4:1996 E

Foreword

The text of document 62/83/FDIS, future edition 1 of IEC 601-1-4, prepared by IEC TC 62, Electrical equipment in medical practice, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as EN 60601-1-4 on 1996-07-02.

The following dates were fixed:

- latest date by which the EN has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 1997-04-01
- latest date by which the national standards conflicting with the EN have to be withdrawn (dow) 1997-04-01

This European Standard constitutes a Collateral Standard to EN 60601-1 : Medical electrical equipment - Part 1: General requirements for safety, hereinafter referred to as the General Standard.

In the EN 60601 series, Collateral Standards specify general requirements for safety applicable to:

- a group of MEDICAL ELECTRICAL EQUIPMENT (e.g. radiological equipment);
- a specific characteristic of all MEDICAL ELECTRICAL EQUIPMENT, not fully addressed in the General Standard (e.g. electromagnetic compatibility).

The numbering of sections, clauses and subclauses of this Collateral Standard corresponds with that of the General Standard.

Subclauses and figures which are additional to those of the General Standard are numbered starting from 201: additional annexes are lettered AAA, BBB, etc, and additional items aaa), bbb), etc.

Annexes designated “normative” are part of the body of the standard.
Annexes designated “informative” are given for information only.
In this standard, annexes AAA and ZA are normative and annexes BBB, CCC, DDD, EEE and FFF are informative.
Annex ZA has been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 601-1-4:1996 was approved by CENELEC as a European Standard without any modification.

In the official version, for annex FFF, Bibliography, the following notes have to be added for the standards indicated:

IEC 812 **NOTE: Harmonized as HD 485 S1:1987 (not modified).**

IEC 1025 **NOTE: Harmonired as HD 617 S1:1992 (not modified).**

Annex ZA (normative)

Normative references to international publications with their corresponding European publications

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. 'For undated references the latest edition of the publication referred to applies (including amendments).

NOTE: When an international publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

Publication	Year	Title	EN/HD	Year
IEC 601-1	1988	Medical electrical equipment Part 1: General requirements for safety	EN 60601-1 + corr. July	1990 1994
A1	1991		A1 + corr. July	1993 1994
A2	1995		A2 A13	1995 1996
IEC 601-1-1	1992	Medical electrical equipment Part 1: General requirements for safety 1. Collateral standard: Safety requirements for medical electrical systems	EN 60601-1-1	1993
IEC 788	1984	Medical radiology - Terminology	HD 501 S1	1988
ISO 9000-3	1991	Quality management and quality assurance standards Part 3: Guidelines for the application of ISO 9001 to the developement, supply and maintenance of software	EN 29000-3	1993
ISO 9001	1994	Quality systems - Model for quality assurance in design development, production, installation and servicing	EN ISO 9001	1994

CONTENTS

MEDICAL ELECTRICAL EQUIPMENT -

Part 1: General requirements for safety -

4. Collateral Standard: Programmable electrical medical systems

SECTION 1: GENERAL

1 Scope, object and relationship to other standards

1.201 Scope

This Collateral Standard applies to the SAFETY of **MEDICAL ELECTRICAL EQUIPMENT** and **MEDICAL ELECTRICAL SYSTEMS** incorporating **PROGRAMMABLE ELECTRONIC SUBSYSTEMS (PESS)**, hereinafter referred to as **PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS).**

NOTE - Some systems which Incorporate software and are used for medical purposes fall outside the scope of this Collateral Standard, e.g. many medical informatics systems. The distinguishing factor/criterion is whether or not the system satisfies the definition of **MEDICAL ELECTRICAL EQUIPMENT** in 2.2.15 of IEC 601-1 or the definition of **MEDICAL** ELECTRICAL SYSTEM in 2 203 Of IEC 601-1-1.

1.202 Object

This Collateral Standard specifies requirements for the process by which a **PEMS** is designed. This Collateral Standard also serves as the basis of requirements of Particular Standards, including serving as a guide to **SAFETY** requirements for the purpose of reducing and managing **RISK.** This Collateral Standard is addressed to:

a) certification bodies;
b) **MANUFACTURERS;**
c) writers of Particular Standards.

This standard covers:

d) requirement specification;
e) architecture;
f) detailed design and implementation including software development;
g) modification;
h) **VERIFICATION** and **VALIDATION;**
j) marking and **ACCOMPANYING DOCUMENTS.**

Aspects not covered by this standard include:

k) hardware manufacturing;
l) software replication;
m) installation and commissioning;
n) operation and maintenance;
o) decommissioning.

1.203 *Relationship to other standards*

1.203.1 *IEC 601-1*

For MEDICAL ELECTRICAL EQUIPMENT, this Collateral Standard complements IEC 601-1 and its amendments.

When referring to IEC 601-1 or to this Collateral Standard, either individually or in combination, the following conventions are used:

– 'the General Standard" designates IEC 601-1 alone;

- 'this Collateral Standard' designates IEC 601-1-4 alone:

- "this Standard" designates the combination of the General Standard and this Collateral Standard.

1.203.2 *Particular Standards*

A requirement in a Particular Standard takes priority over the corresponding requirement in this Collateral Standard.

1.203.3 *Normative references*

The following normative documents contain provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the editions indicated were valid. All normative documents are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

IEC 601-1:1988, *Medical electrical equipment - Part 1: General requirements for safety*
Amendment No. 1 (1991)
Amendment No. 2 (1995)

IEC 601-1-1:1992, *Medical electrical equipment - Part 1: Genera/ requirements for safety - 1. Collateral Standard: Safety requirements for medical electrical systems*

IEC 788: 1984, *Medical radiology - Terminology*

ISO 9000-3: 1991, *Quality management and quality assurance standards - Part 3: Guidelines for the application of ISO 9001 to the development, supply and maintenance of software*

ISO 9001: 1994, *Quality systems - Model for quality assurance in design, development, production, installation and servicing*

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